K081253

C5 medicalwerks

Section 2: 510(k) Summary MAY 15 2008

510(k) Owner: **C5 Medical Werks**
2451 River Road
Grand Junction, CO 81505
Phone No. 970/683-7900
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Contact Person: Homer Gregory
Director, Quality Assurance and
Regulatory Compliance
Phone No. 970/683-7900

Date of Summary: April 2, 2008

Name of Device:

Trade name – ZirDent™ CAD/CAM Blocks

Common name – Dental restorative material, ceramic dental blanks

Classification name – Porcelain powder for clinical use (21 CFR 872.6660). Class II. Product Code EIH.

*Legally marketed devices to which C5 Medical Werks is claiming equivalence:

Katana Zirconia – 510(k) number K050160
ZirBlank PS & FS - 510(k) number: K070045
Zerion - 510(k) number: K061804
Xavex-G100 - 510(k) number: K050903

*510(k) data for these devices is available on FDA's CDRH website.

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Section 2: 510(k) Summary (continued)

Description of device: ZirDent is a pre-formed machineable dental blank composed of zirconia ceramic (yttrium oxide stabilized zirconium oxide [YZTP]). ZirDent is available in green (meaning "unfired") pre-formed blanks, partially-sintered (partially fired) pre-formed blanks and fully sintered (including hot isostatic press) pre-formed blanks. ZirDent is available in different shapes, shades, and dimensions according to the customers'/ dental laboratories' specifications.

Indications for use:
ZirDent is a pre-formed ceramic dental blank intended for CAD/CAM fabrication of zirconia frameworks for all-ceramic dental restorations.

ZirDent is designed for manufacturing ceramic dental restorations such as single crowns or bridgeworks. The ceramic dental blank is machined by the customers/dental laboratories on their milling centers or similar equipment using CAD/CAM techniques for design and processing to the patient-specific anterior/posterior tooth/bridge specification provided by the dental practitioner. For the green and partially-sintered pre-formed blanks, the customer/dental laboratory completes the sintering process after machining the patient-specific crown/bridge.

Summary of technological characteristics: ZirDent is a biocompatible, water insoluble, pre-formed YTZP ceramic dental blank designed to be machined into a crown or bridge per the dental practitioners' specifications. These technological characteristics are identical to the predicate devices noted in this submission.

Substantial equivalence: Testing (including ISO 6872) confirms ZirDent is as safe and effective as the predicate devices noted in this submission.

Conclusion: ZirDent is substantially equivalent to the predicate devices indicated in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2008

C5 Medical Werks, Incorporated
C/O Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K081253
Trade/Device Name: ZirDent™ CAD/CAM Blocks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: April 30, 2008
Received: May 2, 2008

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 1: Indications for Use Statement

510(k) Number: K081253

Device Name: **ZirDent™** CAD/CAM Blocks

Indications for Use: ZirDent™ CAD/CAM Blocks are pre-formed ceramic dental blanks intended for CAD/CAM fabrication of zirconia frameworks for all-ceramic dental restorations (porcelain teeth).

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH,,Office of Device Evaluation (ODE)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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